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10/817,198	04/02/2004	Kim Simelius	4208-4184	2178

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EXAMINER	
WHALEY, PABLO S	

ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
04/15/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/817,198	SIMELIUS, KIM	
	Examiner	Art Unit	
	PABLO WHALEY	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 31-126* is/are pending in the application.

4a) Of the above claim(s) *13,14,20,21,26-28,34,35 and 37-126* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,15-19,22-25,29,31-33 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims Under Examination

Claims 1-12, 15-19, 22-25, 29, 31-33, and 36 are under examination. Claim 30 is cancelled. Claims 13, 14, 20, 21, 26-28, 34, 35, and 37-126 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Withdrawn Rejections

The rejection of claims 1-12, 15-19, 22-25, 29, 31-33, and 36 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's arguments and amendments filed 12/18/2008.

The rejection of claims 1-4, 7-12, 15-17, 19, 22-23, 29, 32, 33, and 36 under 35 U.S.C. 102 (b) and (e) as being anticipated by Eggert et al. (US 6,527,558; Issued Mar. 4, 2003; Filed Aug. 17, 2000) is withdrawn in view of applicant's arguments and amendments filed 12/18/2008.

The rejection of claims 1, 12, 19, and 36 are rejected under 35 U.S.C. 102 (b) as being anticipated by Kohl et al. (Phil. Trans. R. Soc. Lond. A, 2000, Vol. 358, p. 579-610) is withdrawn in view of applicant's arguments and amendments filed 12/18/2008.

The rejection of claims 1, 2, 5-12, 15-19, 22-25, 29, 31-33, and 36 under 35 U.S.C. 103(a) as being unpatentable over Levine (US 2004/0064298; Filed Sep. 26, 2003), in view of Robb et al. (Computerized Medical Imaging and Graphics, 2000, Vol. 24, p.133–151) is withdrawn in view of applicant's arguments and amendments filed 12/18/2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 7-12, 15-17, 19, 22-25, 29, 32, 33, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggert et al. (US 6,527,558; Issued Mar. 4, 2003; Filed Aug. 17, 2000), in view of Varelis et al. (US 5,033,474, Issued Jul. 23, 1991).

The instant claims are now drawn to a method resulting in deducing the condition of a user, wherein deducing takes into account the selected operation mode and wherein the user is informed of the deduced condition, wherein the condition is arrhythmia (as required by Specie A and as in claim 12), wherein the simulated organ is a heart (as required by Specie C and as in claim 19), and wherein a cardiopulmonary system is simulated (as required by Specie B and as in claim 36). For purposes of applying prior art, the term "user" is interpreted as a patient.

Eggert teaches an interactive patient simulator program and virtual instruments for use with the patient simulator [Abstract] and [Fig. 1a]. In particular, Eggert shows operating a patient simulator [Abstract] which includes a simulated organs include the heart, lungs, and other organs [Col. 4, lines 45-50], as in claims 1, 2, 7, 19 and Specie C. Instruments include ECG sensors comprising a multi-lead system for obtaining biological measurement data and means for sensor calibration [Col. 4, lines 35-45], as in claims 1, 3, 4, and 22-23. Eggert shows the selection of arrhythmia modules (i.e. operational modes) [Fig. 5 and Fig. 12] for providing information regarding measured biological data in the form of arrhythmias, treatment, EKG sounds, trace, and exit items [Col. 12, lines 1-15], as in claims 1, 12, 32, and Specie A. Eggert shows the selection of a shock button (i.e. operational mode) for simulating defibrillation shock such that the resultant condition matches biological data [Col. 5, lines 10-20], as in claim 1. Eggert shows simulating the cardiopulmonary system and deducing the condition of a user by manipulation of operational modes [Fig. 18, 20, and 21], as in claims 1, 33, 36 and Specie B. Eggert shows calibrating the interaction between the virtual stethoscope and the simulator using a predetermined realistic body sound when the virtual stethoscope is placed on the correct anatomical position of the

simulator [See Ref. Claim 31]. Eggert shows simulation of the thorax [Fig. 19], as in claim 8. Eggert shows simulating vital signs with a module that simulates a plurality of cardiac rhythms for a user to analyze and determine as normal or abnormal [Col. 15, lines 35-45], as in claims 9, 10, 11, 15, 16, and 17. Eggert shows employing waveform comparison of ECG data for informing a user of the hearts conductive activity [Fig. 23], as in claims 29 and 30.

Eggert does not specifically recite a step for obtaining biological measurement data of a user, as in claim 1 or the use of multiple ECG sensors as in claims 24 and 25.

Varelis teaches a personal health monitor for obtaining data from a patient and transmitting the data for review [Abstract and Col. 1]. The device comprises a computer and sensors for physiological monitoring (e.g. ECG, temperature, blood pressure) and may also be used by the patient for self-monitoring purposes [Col. 1, lines 1-40]. The invention of Varelis allows for transmission of patient data to a physician for diagnosis [Col. 2, lines 1-25]. An advantage of using the personal health monitoring device as taught by Varelis is that is provides a means for involving the patient in his own monitoring thereby reducing health care costs [Col. 2, lines 30-50].

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the method of Eggert to obtain biological measurement data of a user, as taught by Varelis, since the invention of Eggert allows for the incorporation of real patient data and real sensors into the simulator [Col. 4, lines 35-65, and Ref. Claims 9 and 10], resulting in the practice of the instant claimed invention with predictable results. One of ordinary skill in the art would have been motivated to modify the invention of Eggert as set forth above in order to improve patient care by involving the patient in his own monitoring thereby reducing health care costs, as suggested by Varelis [Col. 2, lines 30-50].

Claims 1, 2, 5-12, 15-19, 22-25, 29, 31-33, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine (US 2004/0064298; Filed Sep. 26, 2003), in view of Varelis et al. (US

5,033,474, Issued Jul. 23, 1991), and in view of Siregar et al. (Computers And Biomedical Research, 1998, Vol. 31, p. 323–347).

Levine teaches a virtual patient model for simulating the onset, diagnosis, and treatment of all major medical conditions via a medical instructional console. In particular, Levine teaches operating exemplary simulated organs including a beating heart and lungs, as in claims 1, 2, 7, 11, 17, 19, 33, and 36, and Specie C; simulating a beating heart and showing the heart rhythm and electrical conduction of the heart [Fig. 9 and 10]; selecting an operational mode for generating a virtual patient based on patient data or operational parameters of the selected operational mode [0078] and [0059]; operation modes for simulating normal and abnormal heart rhythms (i.e. arrhythmias) [0084] with a selectable cardiac monitor, wherein rhythms are replications of patient data to simulate an actual human heart [0084], which is a teaching for obtaining data and selecting an operational mode as in claims 1, 2, 12, 32, and Specie A. Levine also shows a communications network for connecting multiple users at multiple computer terminals to the simulation computer comprising simulated organs (i.e. server) [Fig. 3] and [0023] using a wireless communications system [0065], as in claims 5, 6, and 31. Virtual patients with abnormal and normal symptoms for the diagnosis of a medical condition [0072], as in claims 9-11 and 15-17. Simulation of the thorax and monitoring the heart rhythm of a patient [Fig. 7] using three sensors and performing testing including EKGs [0086], as in claims 8, 22, 23, and 25. Displaying information to a user for detecting medical conditions using a diagrammatic schematic showing electrical conduction waveforms within the heart using EKG [0070] and [Fig. 9 and 10], as in claim 29, 30, 31. Simulation of the cardiopulmonary system in a virtual patient [Fig. 14] and [0085], as in claim 36 and Specie B.

Levine does not specifically teach obtaining biological measurement data of a user (i.e. real patient), as in claim 1.

Varelis teaches a personal health monitor for obtaining data from a patient and transmitting the data for review [Abstract and Col. 1]. The device comprises a computer and sensors for physiological monitoring (e.g. ECG, temperature, blood pressure) and may also be used by the patient for self-monitoring purposes [Col. 1, lines 1-40]. The invention of Varelis allows for transmission of patient data to a physician for diagnosis [Col. 2, lines 1-25]. An advantage of using the personal health monitoring device as taught by Varelis is that is provides a means for involving the patient in his own monitoring thereby reducing health care costs [Col. 2, lines 30-50].

Siregar teaches a method for operating a simulated-cardiac model representing a plurality of biological conditions based on patient measurement data, and matching models to patient data [Abstract and p.327, ¶1]. In particular, Siregar shows obtaining real patient data [p.329, lines 3-5] for adjusting parametric models. Siregar shows the operation of a simulated heart in normal and abnormal states [Fig. 10-14]. The user can also interactively select a specific model region of the heart and real patient data obtained from MRI sources using volume rendering software to produce a fusion model for matching real and simulated data [See p.339 and Fig. 2]. Siregar also suggests the incorporation their model viewing system with diagnostic software for comparing a selected model to real patient data [p.339], and suggests that quantitative analysis of ECG data is critical for using non-invasive means for diagnosing patients.

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the method of Levine to additionally obtain biological measurement data as taught by Varelis and Siregar, since the simulated patient data taught by Levine is based on real patient medical data where reactions of the simulated patient correspond with reactions of the real patient's medical history [0025 and 0030]. One of ordinary skill in the art would have been motivated to modify the invention of Levine as set forth above in order improve patient care by involving the patient in his own monitoring thereby reducing health care costs, as suggested by Varelis [Col. 2, lines 30-50], and in order to improve diagnostic models by matching real patient data and simulated data as taught by Siregar [See p.339 and Fig. 2].

Claims 1 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine (US 2004/0064298; Filed Sep. 26, 2003), in view of Varelis et al. (US 5,033,474, Issued Jul. 23, 1991), and in view of Siregar et al. (Computers And Biomedical Research, 1998, Vol. 31, p. 323–347), as applied to claims 1, 2, 5-12, 15-19, 22-25, 29, 31-33, and 36 above, and further in view of Ivlev et al. (Biomedical Engineering, 1995, Vol. 29, No. 6, p.313-314).

Levine, Varelis, and Siregar make obvious a virtual patient model for simulating the onset, diagnosis, and treatment of all major medical conditions, as set forth above.

Levine, Varelis, and Siregar do not specifically teach preprocessing of biological measurement data, as in claim 18.

Ivlev teaches a computer-assisted method for measuring, displaying, and processing 12-lead ECG data to give an automated diagnostic conclusion [p.313, ¶2]. In particular, Ivlev teaches obtaining information on the patient, processing data to suppress ECG artifacts (i.e. preprocessing), interactive mode control, automatic and semiautomatic operation, recognition and measurement of primary amplitude and kinetic parameters, diagnostic decision making, on-line correction of any stage of data acquisition and processing, and display of intermediate and final results of ECG data processing [p.313, ¶3]. Ivlev also teaches comparing measured ECG parameters with diagnostic criteria that takes into account software, literature data, and experimental and clinical findings [p.313, ¶6 and ¶7]. Ivlev also provides a diagnostic algorithm for cardiac rhythm processing [p.314, ¶2].

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the method for deducing the condition of a user made obvious by Levine, Varelis, and Siregar to additionally

preprocess measured data from patients, as taught by Ivlev, because the reduction of artifacts in ECG via processing is critical in the automated diagnostic process, as suggested by Ivlev [p. 313, ¶2, and ¶3].

Response to Arguments

Applicant's arguments, filed 12/18/2008, that Eggert and Levine do not teach obtaining biological measurement data "of a user" have been fully considered and art persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, new grounds of rejections are made in view of applicant's amendment of claim 1 to recite obtaining measurement data "of a user", as set forth above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Pablo S. Whaley/

Patent Examiner

Art Unit 1631

/John S. Brusca/
Primary Examiner, Art Unit 1631